DSJ1&2-PR Exh 529

MEMORANDUM

November 2, 2010

To: Karen Harper

From: Howard Davis

Subject: Suspicious Order Monitoring Program
No. C/S Comp 3.0

Reference is made to Mallinckrodt Standard Operating Procedure (SOP) C/S Comp 3.0 entitled: "Identification and Review of Peculiar Orders" which publishes the Peculiar Order Report for orders in excess of [redacted] The algorithms have been established to identify whether a customer is deviating from a normal order pattern, and/or increasing in frequency.

The Drug Enforcement Administration (DEA) has implemented a strict 'due diligence program' to maintain effective controls and procedures to guard against theft and diversion of controlled substances (21 Code of Federal Regulations 1301.71). It is also a statutory public health and safety registration requirement under Title 21 United States Code (USC) 823 and a basis for revocation of a DEA registration under 21USC824. Under the due diligence program, as published in numerous Federal Register notices and related DEA correspondence to the registrant population, DEA has determined that algorithms and/or arithmetic formulas to define whether an order is suspicious may be failing to detect suspicious orders. Federal Register notices published as early as 2007 (72 Federal Register 36487) state specifically that using formulas that rely on percentages or averages over time has been determined, by the DEA, to be insufficient. The DEA registrant population, especially (but not exclusively) at the wholesale level now must be aware of and implement safeguards to guard against diversion through excessive or suspicious orders. In effect, the DEA has eliminated what was once only a few years ago a suspicious order reporting system that many viewed as absolving liability on the part of the DEA registrant if the order was filled, although suspicious, upon DEA notification.

An order must not be processed and filled if it is either suspicious or excessive. The existing SOP excels to meet this requirement through a specific evaluation process. However, the numeric formula is problematic. For example, should an occasion arise where an order is three times over the historical average for that customer and item or in a situation where the order meets but does not exceed the [redacted] criteria, it would theoretically be filled through normal processing without further question. In doing so in certain cases and as noted in recent immediate suspensions of other large scale DEA registrants, which are all a matter of public record, Mallinckrodt would be unnecessarily exposing itself to potential liability. The fundamental basis of the immediate suspensions in question were suspicious order monitoring deficiencies.

Numeric formulas do not identify circumstances that might be indicative of diversion such as: ordering larger quantities of a limited variety regularly that would otherwise not be viewed as suspicious (like ordering controlled substances with few, if any, other drugs or products whether controlled or non-controlled); ordering highly abused controlled substances in limited quantities disproportionate to other products; or even ordering the same controlled substances from multiple suppliers. DEA's due diligence program requires the registrant population to "know your customer" as part of an effective suspicious order monitoring program to insure that these examples of representative issues are not occurring.

The DEA registrant population as a whole is now required to consider the totality of the circumstances when evaluating an order prior to it being filled, just as the DEA will do in determining if the registrant is operating within the public interest within the meaning of 21USC823 and 824, which are the statutory requirements for obtaining a DEA registration and grounds for denial, suspension or revocation. While not all inclusive, recommended customer inquiries may include such factors as:

- What percentage of business do controlled substances constitute?
- Is the customer complying with other federal, State, local requirements/laws?
- Is the customer soliciting and/or supplying customers via the Internet unlawfully?
- Does the customer have a business relationship with a physician or other business partner who authorizes prescriptions over the Internet?
- Are prescribing practitioners licenses in the State where the controlled substances are being shipped?
- Are shipments made where the majority of the ultimate customers are serviced from the same practitioner who routinely authorizes "cocktail" prescriptions, i.e., drug combinations that compound or have an antagonistic effect?
- Are controlled substances sold to retail outlets that further dispense them without a prescription?
- Does the customer sell controlled substances for market prices or well above state-of-the-art pricing modules?
- Are sells made to customers, or their customers, on a cash only basis or are insurance plans accepted?

Therefore, I recommend the immediate revision of SOP No. C/S Comp 3.0 to include additional definitive criteria, as noted above, such that a more vigilant determination can be made whether the order is suspicious and/or excessive prior to filling any order, in concert with numeric formulas already in place as the Company deems appropriate. Thus, the Company can assure and reference procedures that insure regulatory and statutory compliance with the public interest provisions under the Controlled Substances Act as circumstances warrant upon request. A new draft SOP entitled: "Due Diligence Procedures and Monitoring of Controlled Substances Sales" is included for consideration as a replacement or to be used in addition to the current SOP on file to comply with the DEA's newest interpretation of enhanced and certainly more strict due diligence requirements.